SEP 1 9 2001

K012047

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet, Inc.
56 E. Bell Drive
Warsaw, Indiana 46582

Contact Person: Mary L. Verstynen
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: *3i*® Calcium Sulfate Bone Cement

Common Name: calcium sulfate dihydrate

Classification Name: Implant, endosseous for bone filling and/or reconstruction (872.3640)

Legally Marketed Device To Which Substantial Equivalence Is Claimed:
CAPSET® Calcium Sulfate Bone Graft Plaster

Device Description: *3i*® Calcium Sulfate Cement is packaged in two syringes. One syringe contains the powder component while the other syringe contains the liquid component. The powder component is calcium sulfate dihydrate ($CaSO_4 \cdot 2H_2O$). The liquid component is a solution comprised of potassium citrate monohydrate ($K_3C_6H_5O_7 \cdot H_2O$), sodium phosphate dibasic ($Na_2HPO_4 \cdot 7H_2O$), and distilled water (H_2O). The syringe with the liquid component comes with a female-female Luer coupler for connecting the two syringes together for mixing. When mixed, the powder and liquid combine to form a homogenous paste. The paste hardens approximately 5-10 minutes after the start of mixing.

Intended Use: *3i*® Calcium Sulfate Bone Cement is used over a filled defect providing a stable barrier to graft material migration and is also indicated for use as a binder of bone graft particles.

Summary of Technologies: The cement has the same technological characteristics as the predicate device

Non-Clinical Testing: *3i*® Calcium Sulfate Cement is biodegradable and in animal studies, depending on the defect size, was found to resorb in approximately four to eight weeks. Biocompatibilty testing and animal studies demonstrate the safety of the material, which was found to be non-toxic, non-mutagenic, non-hemolytic, and non-pyrogenic.

Clinical Testing: Not performed on this device.

3i is a registered trademark of Implants Innovations, Inc.
Capset is a registered trademark of Lifecore Biomedical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Implant Innovations, Incorporated
C/O Ms. Mary L. Verstynen
Biomet, Incorporated
56 East Bell Drive
Warsaw, India 46582

Re: K012047
Trade/Device Name: 3I Calcium Sulfate Bone Cement
Regulation Number: None
Regulation Name: Calcium Ulfate Dihydrate
Regulatory Class: Unclassified
Product Code: LYC
Dated: June 22, 2001
Received: June 29, 2001

Dear Ms. Verstynen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

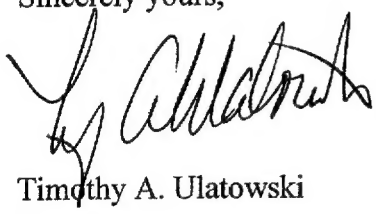
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012047

510(k) NUMBER (IF KNOWN): K012047

DEVICE NAME: *3i*® Calcium Sulfate Bone Cement

INDICATIONS FOR USE:

3i®'s Calcium Sulfate Bone Cement is used over a filled defect providing a stable barrier to graft material migration and is also indicated for use as a binder of bone graft particles.

For use in dental applications only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012047